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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,759	01/30/2002	Adam Lerner	701586/50174-DIV	8480

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/060,759

Applicant(s)

LERNER, ADAM

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4-4-05; 5-4-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's Amendment filed April 4, 2005 is acknowledged. Claims 1-7 and 15 remain under consideration. A Declaration of Dr. Adam Lerner is noted. A Supplemental Amendment filed May 4, 2005 is further acknowledged wherein a Terminal Disclaimer is presented.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

There presently are no composition claims.

Claims 1-7 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,399,649 in the last Office Action.

Subsequent to the filing and acceptance of a Terminal Disclaimer, this rejection of record is withdrawn.

In the last Office Action claims 1-7 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the administration of rolipram and 4-(3-Butoxy-4-methoxybenzyl)-2-imidazolidinone, does not reasonably provide enablement for any type 4 cyclic adenosine monophosphate inhibitor. It was asserted the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In view of the Lerner Declaration and Applicants' argument that members of the class of PDE4 inhibitors behave alike in a wide range of functional assays and in their use to treat different conditions, this rejection of record is withdrawn.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vassallo et al., Mayo Clinic Proceedings.

Vassallo teaches the administration of theophylline, a cyclic adenosine monophosphate phosphodiesterase (PDE) inhibitor, to induce apoptosis in chronic lymphocytic leukemia (CLL) cells. See page 351. The claims differ in that Vassallo encompasses the inhibition of PDE isoenzymes PDE I to VII, with emphasis given to PDE type IV being predominantly expressed by inflammatory cells. See the first column, lines 6-10, on page 347. Therefore, in view of the teachings of Vassallo, one skilled in the hematology art would have been motivated to administer theophylline, a PDE inhibitor of multiple isoenzymes, to treat a patient having symptoms of chronic lymphocytic leukemia. Such would have been obvious in the absence of evidence to the contrary, because theophylline is well established in the prior art as an inhibitor of multiple isoenzymes of PDE with particular efficacy in inflammatory conditions. A therapeutic effect in a patient having symptoms of chronic lymphocytic leukemia would have been a reasonable conclusion because theophylline induces apoptosis and CLL is an inflammatory process. Vassallo suggests a new potential application for theophylline, a drug that has been given through various modes of administration for decades. All patient populations having CLL, such as those who are naïve,

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immunocompromised or unresponsive to chemotherapy with alkylating agents, would reasonably be included in the teachings of the reference.

The elected species, 4-(3-Butoxy-4-methoxybenzyl)-2-imidazolidinone, also known as Ro-1724, recited in claim 15, appears to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

Phyllis Spivack
PHYLLIS SPIVACK
PRIMARY EXAMINER

July 21, 2005